

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: John D. Pruitt et al.

Title: SOLID DOSAGE FORMS COMPRISING PULLULAN

Appl. No.: 10/705,227

Filing Date: 11/12/2003

Examiner: Unassigned

Art Unit: 1615

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Mail Stop MISSING PARTS  
Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98, except as noted below.

The USPTO has waived the requirement under 37 CFR 1.98(a)(2)(i) to submit copies of U.S. patents and U.S. patent application publications when citing and submitting an Information Disclosure Statements in a patent application filed after June 30, 2003 and in an international application that has entered the national stage under 37 USC §371 after June 30, 2003. Accordingly, copies of these types of documents are not being supplied in connection with this application. Reference is being made to Pre-OG Notice from Office of Patent Legal Administration dated July 25, 2003, *Information Disclosure Statements May Be Filed Without Copies of U.S. Patents and Published Applications in Patent Applications filed after June 30, 2003.*

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date Apr. 1 22, 2004

By Michele M. Simkin

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<p style="text-align: center;">Substitute for form 1449B/PTO</p> <p style="text-align: center;"><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p style="text-align: center;">(use as many sheets as necessary)</p>				<b>Complete if Known</b>	
<p style="text-align: right;">APR 22 2004 U.S. PATENT AND TRADEMARK OFFICE</p>				<b>Application Number</b> 10/705,227 <b>Filing Date</b> 11/12/2003 <b>First Named Inventor</b> John D. Pruitt <b>Group Art Unit</b> 1615 <b>Examiner Name</b> Unassigned <b>Attorney Docket Number</b> 029318-0985	
1	of	3			

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code <sup>2</sup> (if known)			
A1	4,178,695			ERBEIA	12/18/1979	
A2	4,616,047			LAFON	10/07/1986	
A3	4,642,903			DAVIES	02/17/1987	
A4	4,783,484			VIOLANTE ET AL.	11/08/1988	
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Examiner Signature		Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

<sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached.

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INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT

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## Complete if Known

Application Number	10/705,227
Filing Date	11/12/2003
First Named Inventor	John D. Pruitt
Group Art Unit	1615
Examiner Name	Unassigned

Attorney Docket Number 029318-0985

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A42	5,518,902	OZAKI ET AL.	05/21/1996	
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Examiner  
SignatureDate  
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				Examiner Name	Unassigned
(use as many sheets as necessary)				Attorney Docket Number	029318-0985
Sheet	3	of	3		

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#### FOREIGN PATENT DOCUMENTS

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		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
A105	WO	02/098565		A1	ELAN PHARMA INTERNATIONAL LIMITED	12/12/2002		
A106	WO	98/14179		A1	CIMA LABS INC.	04/09/1998		
A107	WO	98/46215		A1	CIMA LABS INC.	10/22/1998		
A108	EP	0 636 365		A1	MCNEIL-PPC, INC.	02/01/1995		

#### NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	A109	FDA/CFSAN: Agency Response Letter: GRAS Notice No. GRN 000099, August 1, 2002, <a href="http://vm.cfsan.fda.gov/~rdb/opa-g099.html">http://vm.cfsan.fda.gov/~rdb/opa-g099.html</a> , 5 pgs., obtained online 04/20/2004.	
	A110	Jakovljevi et al., "Fine Structural Analysis of the Fungal Polysaccharide Pullulan Elaborated by Aureobasidium pullulans, CH-1 Strain", <i>J. Serb. Chem. Soc.</i> , 66(6):377-383 (2001).	

Examiner Signature		Date Considered
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